CoaguChek® XS System

User Manual

www.americanscreeningcorp.com

This is a CLIA waived system.

Roche

Table of Contents

About this Manual **1**

Symbols and Abbreviations 1

User Resources **2**

Video 2
Getting Started 2
User Manual 2
Test Strip Package Inserts 2

The CoaguChek XS System **3**

Anticoagulation Medication 3
Blood-clotting Time 3
How the System Works 4
The CoaguChek XS Meter 5
Operating Conditions 6

Getting Started **7**

Batteries 7
Installing (or Replacing) Batteries 8
Meter Setup 9
Setting the Date and Time 9
Code Chip 12
Inserting a New Code Chip 12
Integrated Quality Controls 14

Testing a Blood Sample **15**

Tips for a Good Fingerstick 15
Important Notes about Blood Testing 16
Always 16
Never 16
Infection Control 17
Preparing for a Test 18
Performing a Test 20
Out of Range Values 24
Optional Testing Methods 25
Using Capillary Tubes 25
Using Venous Blood 28

Memory **30**
Storing Test Results in Memory 30
Reviewing Stored Test Results 30
Erasing Stored Test Results 32

Cleaning the Meter **34**
Cleaning the Exterior 34
Cleaning the Test Strip Guide 35

Advanced Features **37**
Setting Advanced Features 38

The Meter's Display **39**

Error Messages **40**
Error Messages You May See After You Apply Blood 44

Other Information **48**
Ordering Information for Health Care Professionals 48
Product Limitations 48
Product Specifications 49
Support/Services 50
Symbols 51
Warranty 54

About this Manual

Symbols and Abbreviations

The test strip insert, the label on the back of the meter, the User Manual, and other packaging material may contain the following symbols or abbreviations:

Use by/Expiration date

LOT

Lot number

IVD

For in vitro diagnostic use

CE 0088

This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices

REF

Catalog number

Please read instructions for use

Caution (refer to accompanying documents). Please refer to safety-related notes in the manual accompanying this instrument

Manufacturer

Store at

User Resources

Several resources are available to help you use and maintain the CoaguChek XS System.

Video (DVD Format)

The CoaguChek XS System Video is for new users of the CoaguChek XS System. The video will help you get comfortable with the CoaguChek XS Meter and the testing procedure.

Getting Started

The Getting Started guide shows you how to perform your first coagulation test on the CoaguChek XS Meter.

User Manual

This CoaguChek XS System User Manual is a comprehensive guide to the meter and test strips. It is designed to provide answers to your questions about the meter's operation and use. **Read this entire manual carefully, and refer to it as necessary.**

Test Strip Package Inserts

Be sure to read the test strip package insert for important updates and keep the insert from your current test strip package for future reference.

The CoaguChek XS System

The CoaguChek XS System is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The CoaguChek XS System uses fresh capillary or nonanticoagulated venous whole blood.

Anticoagulation Medication

Anticoagulation medications, also known as blood thinners, are prescribed to avoid unwanted clots. Blood-clotting time must be monitored to ensure that a patient's medication dosage is correct.

Blood-clotting Time

The rate at which blood clots is measured in units called INR. It is very important for patients to stay within their target INR range. If the INR is too low, the risk of blood clots increases. If the INR is too high, the risk for internal bleeding increases.

Everyone's INR is different. The patient's doctor determines the best INR range for the patient, depending on why the patient is taking anticoagulants and how the patient reacts to them. The doctor also determines how often the patient's blood should be tested. The doctor needs to know the patient's blood-clotting time in order to successfully treat the patient.

How the System Works

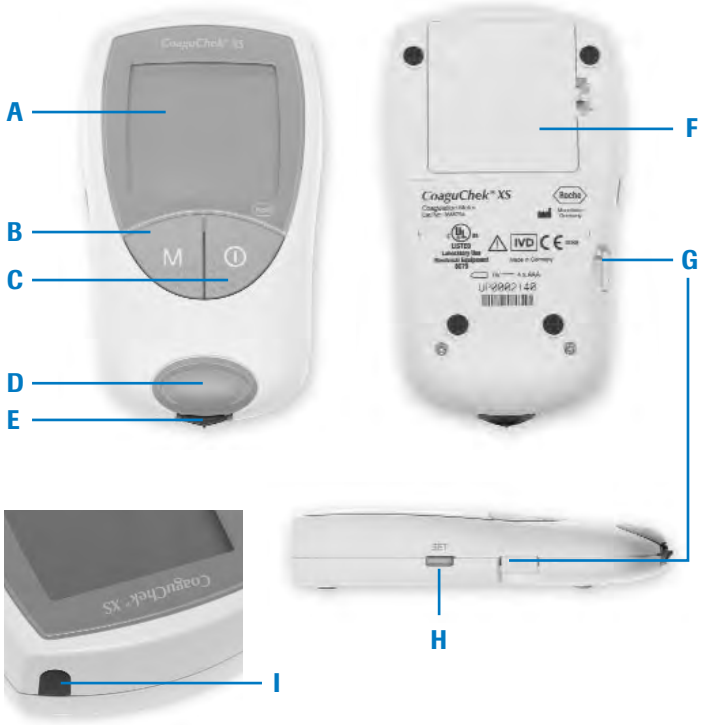
The CoaguChek XS System includes a meter and CoaguChek XS PT test strips. Each box of test strips has its own code chip that you insert into the meter. The code chip contains important information about the test strips such as their expiration date and lot number. The meter and test strips work together to provide a safe and reliable system for testing blood-clotting time.

The CoaguChek XS System makes measuring blood-clotting time easy. The display on the meter guides you through the testing process. With the code chip inserted in the meter, you simply insert a test strip and apply a blood sample. The meter displays the result in about a minute. The meter automatically stores the result in memory so that you can easily recall results.

The CoaguChek XS PT test strip contains various ingredients. When a blood drop is applied, the meter starts the test and the blood mixes with the ingredients on the test strip. When the meter determines that the blood has clotted, it stops the measurement and calculates the result.

The CoaguChek XS Meter

A **Display**
B **M (Memory) Button**
C **ON-OFF Button**
D **Test Strip Guide Cover**
E **Test Strip Guide**
F **Battery Compartment Cover**
G **Code Chip Slot**
H **SET Button**
I **Data Port**



Operating Conditions

To ensure that the CoaguChek XS Meter functions correctly, follow these guidelines:

- Use the meter at room temperature, between 65°F and 90°F (18°C and 32°C).
- Use the meter at a relative humidity of less than 85%, without condensation.
- When testing, keep the meter level.
- If you store the meter for a period of time, remove the batteries.
- Do not use the meter at an altitude higher than 14,000 feet (4,300 meters).
- Do not use the meter near a strong magnetic field, such as a microwave oven, as this may interfere with the meter's proper operation.

Note: The CoaguChek XS Meter automatically shuts off after 3 minutes if no buttons have been pushed.

Getting Started

Refer to the Getting Started guide to learn how to set up the meter and prepare for and run your first blood-clotting-time test.

Batteries

The CoaguChek XS Meter uses 4 AAA batteries. The recommended batteries, alkaline-manganese batteries, should last for approximately 60 tests.

When you turn the meter on, the display briefly shows the battery symbol. The battery symbol is divided into 4 segments. With new, fresh batteries in the meter, the battery symbol shows all 4 segments.

When only 1 segment appears, replace the batteries. When only 1 segment appears you can still access results stored in the meter's memory.

If you insert new batteries within 1 minute of removing the old batteries, the date and time settings will remain in memory. But if you do need to reset the date and time, refer to the Meter Setup section in this manual.

The meter saves battery power by automatically turning off after 3 minutes, unless you press a button or insert a test strip. Even when the batteries are removed, the test results are saved in memory.

Installing (or Replacing) Batteries

Have ready 4 AAA batteries.

1. Open Battery Compartment

With the meter turned off, turn it over. Press the latch gently inward and lift the cover. Remove the old batteries, if necessary.

2. Insert New Batteries

Position the batteries according to the diagram inside the battery compartment. Replace the cover. Turn the meter back over.

3. Turn Off

Turn the meter off ⏻.

Meter Setup

The CoaguChek XS Meter is preset with the U.S. date format (month-day-year) and U.S. time format (12-hour as opposed to 24-hour).

Before you use the meter for the first time–or if there is no battery power for more than 1 minute–you'll have to set the current date and time. In addition, the meter has certain advanced features that you can set up if you plan to use them. See the Advanced Features section in this manual to learn more about the advanced features and how to set them up.

Setting the Date and Time

The date and time settings are important. Each time you run a test, the meter compares its date with the test strip's expiration date. If the test strips are expired, the meter displays an error message and prevents you from running a test.

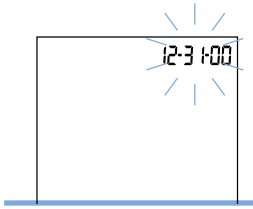
Whenever you put batteries in the meter, it automatically goes to Setup mode (where you set the date and time). You can also go to Setup mode at any time by pressing the SET button ▭.

To set the date and time, you'll use these buttons:

- M to change a setting.
- ▭ to accept a setting.

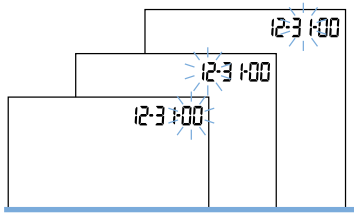
1. Go to Setup Mode

If the meter is not already in Setup mode, press the SET button ▭.



The date format flashes in the upper-right corner.

2. Set Today's Date

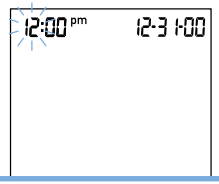


Press the SET button ▭.

Press the M button Ⓜ to change the year. Press the SET button ▭.

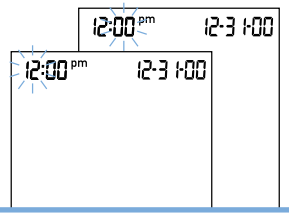
Press the M button Ⓜ to change the month. Press the SET button ▭.

Press the M button Ⓜ to change the day. Press the SET button ▭.



The time format flashes in the upper-left corner.

3. Set Current Time



Press the SET button ▭.

Press the M button Ⓜ to change the hour. Press the SET button ▭.

Press the M button Ⓜ to change the minutes. Press the SET button ▭.

4. Turn Off

Turn the meter off ⏻.

Code Chip

Each box of test strips comes with its own code chip. The code chip provides the meter with information such as the lot number and expiration date of the test strips.

Before each test, make sure the correct code chip is in the meter. Each time you open a new box of test strips, replace the old code chip with the new one.

Protect the code chip from moisture and also from equipment that produces magnetic fields, such as a microwave oven.

Inserting a New Code Chip

Have the correct code chip ready.

1. Remove Old Code Chip

With the meter turned off, remove the old code chip and throw it away.

2. Match Codes

Make sure that the three-number code on the new test strip container matches the three-number code on the new code chip.

3. Insert New Code Chip

Slide the new code chip into the code chip slot until it snaps into place.

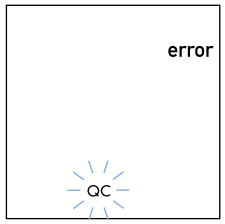
Testing a Blood Sample

Integrated Quality Controls

The CoaguChek XS System has quality control functions integrated into the meter and test strips, so you never have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test.

When the quality control test runs, the letters **QC** flash on the meter's display. When the quality control test completes, a checkmark (✓) appears following the letters **QC**. Then the meter continues to run the blood test.

If the quality control test fails, the meter displays the following error message. See the Error Messages section in this manual for an explanation of this (and other) error messages and what to do when they occur.



Tips for a Good Fingerstick

For fingerstick blood testing, increasing the blood flow in the finger will help you get a good drop of blood. Before you prick the finger, try the following techniques until you see that the fingertip has good color:

- Warm the hand by having the patient hold it under his or her armpit, use a hand warmer, and/or wash the hand with warm water.
- Have the patient hold his or her arm down to the side, so that the hand is below the waist.
- Massage the finger from its base.

If needed, immediately after pricking, gently squeeze the finger from the base to encourage blood to flow.

Important Notes About Blood Testing

Always

- Operate the meter at temperatures between 65°F and 90°F (18°C and 32°C).
- Refer to the test strip package insert for proper use and handling of test strips.
- Keep the test strip guide and meter clean. You may occasionally need to clean them. See the Cleaning the Meter section in this manual for more information.

Never

- Store the meter in damp or humid conditions (greater than 85% humidity).
- Remove or insert the code chip while the meter is performing a test.
- Use a code chip from a box of test strips other than the one in use.
- Open a vial of test strips or touch a test strip with wet hands or gloves.
- Touch or remove the test strip during a test.
- Wait more than 15 seconds after sticking the fingertip before applying the blood.
- Add more blood after the test has begun.
- Touch any buttons while a test is in progress.
- Perform a test with a drop of blood from a previous fingerstick.

Infection Control

Follow appropriate infection control guidelines.

- Use gloves.
- Use a separate lancet for each person.
- Dispose of used lancets and test strips in a stable container with a lid according to infection control guidelines.
- Follow all other hygiene and safety procedures applicable.

Caution: There is a potential risk of infection. *Medical staff and other persons using the CoaguChek XS Meter to perform tests on more than one patient must be aware that any object coming into contact with human blood is a potential source of infection. (See: National Committee for Clinical Laboratory Standards: Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue. Approved Guideline, NCCLS document M29-A, 1997.) Dispose of used items according to the disposal policy of your facility.*

Preparing for a Test

1. Gather Items

Gather the following items:

- CoaguChek XS Meter
- Container of test strips
- Test strip code chip
- CoaguChek lancet

Each box of test strips comes with a matching code chip. Every time you open a new box of test strips, you must replace the code chip.

2. Match Codes

Make sure the code number on the test strip container and the code chip match.

3. Insert Code Chip

Make sure the meter is turned off. With the code number facing up, insert the code chip into the code chip slot until it snaps into place.

4. Wash Hands

Have the patient wash his or her hands in warm, soapy water. Or, clean the fingertip with an alcohol wipe.

Make sure the fingertip is thoroughly dry.

Performing a Test

1. Get Ready

Take a test strip out of the container.

Close the container tightly.

Do not open a vial of test strips or touch a test strip with wet hands or gloves. This may damage the test strips.

You have 10 minutes to use a test strip once you remove it from the container.

2. Insert Strip

Slide the test strip into the test strip guide in the direction of the arrows until it stops.

The meter turns on. The code number of the inserted code chip flashes on the display.

3. Match the Code

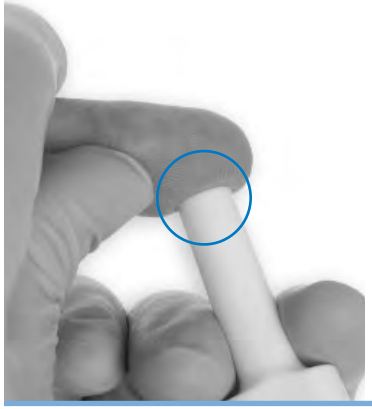
Confirm that the number displayed matches the number on the test strip container, then press M M.

If the numbers are different, make sure you are using the code chip that came with the test strips you are using.

An hourglass appears as the meter warms up, which takes about thirty seconds

When the meter is warmed up a flashing test strip appears and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.

4. Collect the Blood



Twist the protective cap off the CoaguChek lancet.

Massage the finger until you see increased color in the fingertip.

Keeping the hand down, press the tip of the lancet firmly against the side of the fingertip. Press the blue trigger button.

Gently squeeze from the base of the finger to develop a hanging drop of blood.

5. Identify the Target Area

Find the target area on the test strip.

You can dose the target area by bringing the patient's finger to the top of the test strip or by bringing the meter to the patient's finger so that the side of the test strip touches the blood drop.

6. Apply the Blood

Within 15 seconds of sticking the fingertip, apply the blood to the target area of the test strip—either from the top or side of the test strip.

Hold the blood drop to the test strip until you hear a beep. The flashing blood drop symbol disappears.

Do not add more blood to the test strip. Do not touch the test strip.

The result appears in about 1 minute.

7. Record Result

Record the result according to your facility's guidelines.

8. Clean Up

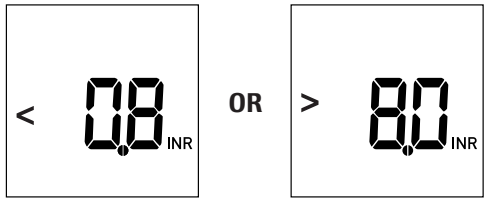
Place the used test strip and lancet in an approved container. Turn the meter off .

If the meter is dirty, wipe it clean with a CoaguWipe™ Bleach Towel or other recommended cleaner.

Out of Range Values

The CoaguChek XS PT test strips provide test results if the INR value is between 0.8 and 8.0. If the result falls outside of this range, the meter displays < (less than) **0.8** or > (greater than) **8.0**. If the meter indicates an out-of-range value, refer to the test strip package insert and repeat the test.

In rare cases, Error Message 7 can occur in patients with long coagulation times (> 8 INR). If this error message appears again when the test is repeated, the result must be checked using another method.



Optional Testing Methods

Using Capillary Tubes

You may use capillary tubes to collect the blood from a fingerstick and to dose the test strip. Use only CoaguChek Capillary Tubes/Bulbs, Cat. No. 11621173001. Do not use glass capillary tubes or capillary tubes that contain anticoagulants.

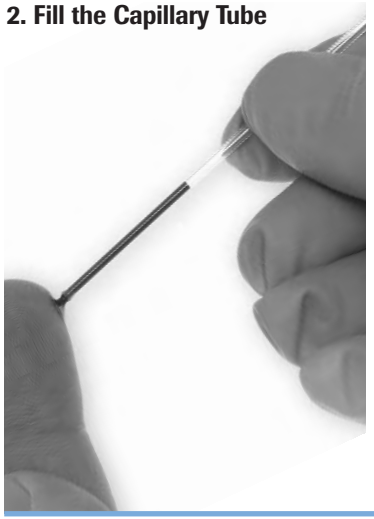
The following steps are optional to the fingerstick blood sample instructions in the Preparing for a Test and Performing a Test sections of this manual.

1. Prepare the Capillary Tube

Firmly insert the end of the capillary tube into the capillary bulb. Completely insert the tube into the bulb to break the bulb diaphragm.

Do not push the capillary tube in so far that it extends beyond the top of the bulb.

2. Fill the Capillary Tube



When the flashing test strip appears on the meter's display, stick the fingertip. Then touch the capillary tube to the blood drop. Keep the tube level, and allow it to fill by capillary action. Fill the tube only halfway.

Avoid getting air bubbles into the sample. Do not touch the hole at the top of the bulb. If blood gets into the bulb during sample collection, discard the bulb and repeat the test with a new test strip and fingerstick.

3. Dose the Test Strip

Within 15 seconds of sticking the fingertip, apply the blood to the test strip. Put your finger over the hole at the end of the capillary tube. Hold the capillary tube directly over the target area of the test strip. Squeeze the bulb to dispense one hanging drop of blood.

Do not touch the test strip, move the meter, or add more blood during testing.

4. Record Result

Record the result according to your facility's guidelines.

5. Dispose of Blood Collection Items

After testing, discard the capillary tube along with the used test strip and lancet according to infection control guidelines.

Using Venous Blood

You may use the CoaguChek XS Meter to test venous blood. Blood may be collected directly using a butterfly or a needle and syringe. Do not clean the syringe tip with alcohol or water prior to dosing the test strip. Use only a plastic syringe free of anticoagulant. Do not use glass. The syringe needle should be 23 gauge or larger. A 21 gauge or larger needle is recommended.

Note: Refer to the Preparing for a Test and Performing a Test sections of this manual for fingerstick blood testing instructions.

1. Collect the Venous Sample

When the flashing test strip appears on the meter's display, collect the venous blood sample.

Do not perform venipuncture until the flashing test strip is displayed.

2. Dose the Test Strip

Discard the first 4 drops of blood. Then immediately place 1 hanging drop of blood directly onto the target area of the test strip. Completely cover the target area.

Do not touch the test strip. Do not introduce air bubbles, move the meter, or add more blood during testing.

3. Record Result

Record the result according to your facility's guidelines.

4. Dispose of Blood Collection Items

After testing, discard the needle, syringe, or butterfly, and used test strip according to infection control guidelines.

Memory

Storing Test Results in Memory

The CoaguChek XS Meter automatically stores up to 100 test results and their dates and times in its memory. If the memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved.

Note: All test results, including their date and time, remain in memory even when the meter is without batteries.

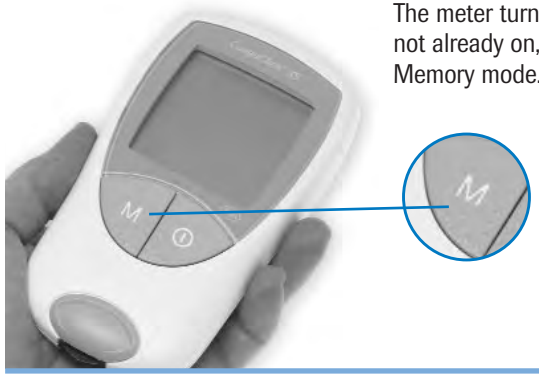
Reviewing Stored Test Results

You can review stored test results even when the meter's battery power is low.

To review results in memory:

1. Access the Memory

Press the M button M. The meter turns on, if it is not already on, and goes to Memory mode.



2. View Most Recent Result

The most recent test result appears. The letters **mem** indicate that you are viewing a result in memory. The time and date of the test also appear. If there are no results in memory, a **0** appears in the display's top-right corner.

3. View Earlier Results

To view earlier results, press the M button again M. After you have viewed all the results in the memory, 3 dashes appear.

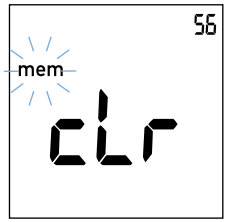
Erasing Stored Test Results

You can erase all of the test results that are stored in the meter's memory. You cannot, however, erase individual test results.

To erase all stored results:

1. Go to Erase mode.

With the meter turned off, press **and hold down** the M button M. While you are holding down the M button, press the ON-OFF button ⏻ and then hold down both buttons for at least 5 seconds.

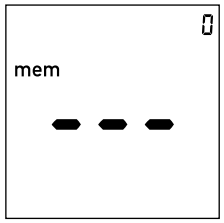


The meter displays **mem** (flashing) and **clr**. The number of results in memory is shown in the top-right corner of the display.

2. Confirm

Press the M button M to confirm that you want to erase the entire memory.

Note: To exit Erase mode without erasing the results, press the ON-OFF button instead.



The hourglass symbol flashes while the test results are being erased. Then, the counter is set to **0** and 3 dashes appear.

Cleaning the Meter

It is important to keep the meter clean. Clean the meter whenever it looks dirty or, if you prefer a regular schedule, clean the meter each time you open a new box of test strips.

Use only the following products to clean the meter:

- CoaguWipe Bleach Towels or other pre-packaged bleach towelettes
- 10% bleach solution (1 part bleach and 9 parts water)
- 70% isopropyl alcohol solution
- lint-free tissues
- cotton swabs

Caution: Do not spray any cleaning solution on the meter. Never use a spray of any type.

Cleaning the Exterior

1. Clean the Exterior

With the meter turned off, wipe the meter's exterior clean.

2. Dry the Exterior

With a lint-free tissue, dry the meter.

Cleaning the Test Strip Guide

1. Open the Cover

With the meter turned off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean.

2. Clean the Test Strip Guide

Clean the easily accessible areas with a cotton swab.

Caution: Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.

3. Allow to Dry

With the cover off, allow the test strip guide to dry for about 10 minutes.

4. Close the Cover

Close the cover, and make sure it snaps into place.

Advanced Features

The CoaguChek XS Meter includes advanced features that you can set up as necessary. They are:

- Changing the unit of measurement
- Turning off the beep (With the beep turned on, the meter beeps when it detects a test strip, when it is ready for you to apply a sample, when it detects a sample, when the result is displayed, and when an error occurs–3 short beeps.)
- Setting a therapeutic range (for INR only)

The following table shows the setting options and the default setting for each advanced feature:

Feature	Setting Options	Default Setting
Unit	%Q Sec INR	INR
Beep	On Off	On
Therapeutic range (for INR only)	On Off	Off
Set range (in INR)	Lower range (1.5 – 3.5) Upper range (2.5 – 4.5)	1.5 INR 2.5 INR

Setting Advanced Features

You can access these settings by going to Setup mode. To go to Setup mode, press the SET button ▭. The date format, flashing, will appear. Once you are in Setup mode, you'll use these buttons:

- M to change a setting
- ▭ to accept a setting (and move on to the next setting)

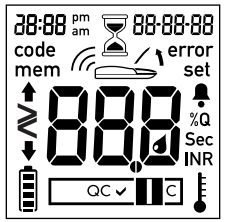
Note: When you go to Setup mode, the date format, date, time format, and time settings appear first. Press the SET button ▭ to move past the date and time settings to get to the advanced settings.

The Meter's Display

When you turn the meter on, it briefly shows all the display's letters, numbers, and symbols. Regularly check that all segments of each letter, number, and symbol appear. Please compare your meter's display to the meter display shown here on this page.

You can display all the letters, numbers, and symbols for a longer time to allow comparison. To do this, you will turn the meter on and then hold down the ON-OFF button ⏻.

The full display should appear as follows:



Error Messages

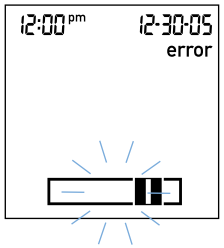
You may see the following error messages while using the CoaguChek XS Meter. If you see an error message, first try to correct the problem using the solution described below. If the problem persists, call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week.

Error: Test Strip

A test strip was already inserted when the meter was turned on. If you did not remove the test strip after the last test, you will see this error. This error could also occur if the meter timed out after you inserted the test strip.

The test strip is unusable.

The test strip is not a CoaguChek XS PT test strip.

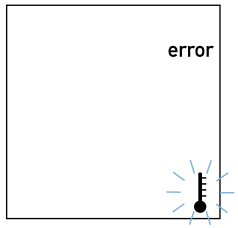


Solution:

Remove the test strip. Then repeat the test with a new CoaguChek XS PT test strip.

Error: Meter Temperature

The meter is too cold or too warm to measure correctly.

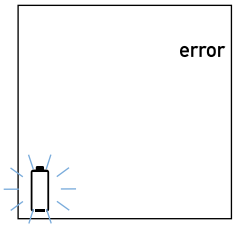


Solution:

Turn the meter off and allow it to stand for about 30 minutes at room temperature (between 65°F and 90°F).

Error: Battery

The battery level is too low.



Solution:

Replace the batteries. See the Batteries section of this manual.

Error: Test Strip Guide Cover

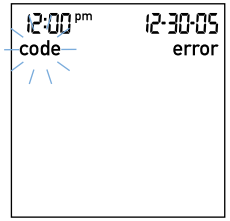
The test strip guide cover is not properly closed.

Solution:

Close the test strip guide cover.

Error: Code Chip

The code chip is missing, not properly inserted, or damaged.



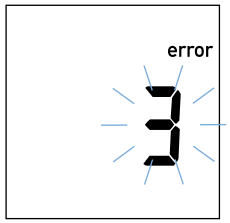
Solution:

Check to see if you have the correct code chip properly inserted in the meter. For more information, see the Code Chip section of this manual.

If the code chip is damaged, call Roche Diagnostics Technical Service Center at 1-800-428-4674.

Error: Test Strip Expired

The test strip has expired.



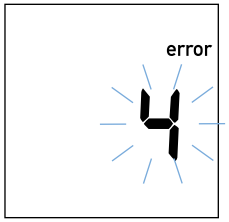
Solution:

Check the meter's date setting. If it is not correct, set the correct date. For more information, see the Meter Setup section of this manual.

If the date is correct, turn the meter off and remove the code chip and the test strip. Then use the code chip and a test strip from a new box of test strips.

Error: Test Strip Unusable

The test strip is unusable.



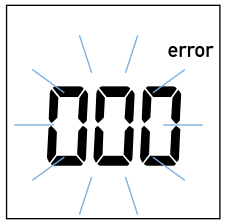
Solution:

Turn the meter off, remove the test strip, and then re-insert it. If the error message reappears, discard the unusable test strip and use a new one.

Error Messages You May See After You Apply Blood

Error: Time Exceeded

You did not apply blood to the test strip within 2 minutes after the blood drop symbol appeared.

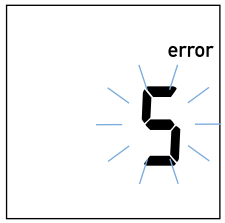


Solution:

Turn the meter off and remove the test strip. Repeat the test using the same test strip and blood taken from a new fingerstick from a different finger.

Error: Blood Application

Error applying blood to the test strip.



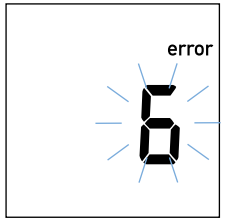
Solution:

Turn the meter off and remove the test strip.

Repeat the test using a new test strip and blood taken from a new fingerstick from a different finger.

Error: Test Strip Interference

The test strip was touched or removed during the test.



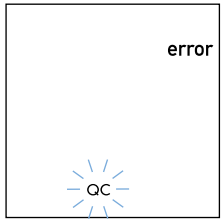
Solution:

Turn the meter off and remove the test strip. Repeat the test using a new test strip and blood taken from a new fingerstick from a different finger.

Do not touch or remove the test strip when a test is in progress.

Error: Quality Control Failure

The test strip failed the internal quality control check. The test strip is unusable.

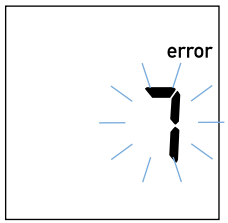


Solution:

Turn the meter off and remove the test strip. Repeat the test using a new test strip and blood taken from a new fingerstick from a different finger.

Error: Measurement Error

Measurement error caused by the blood sample.



Solution:

Do not touch or remove the test strip when a test is in progress.

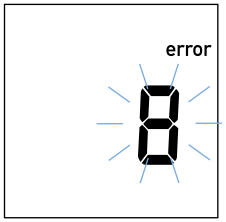
Be sure to apply the blood drop to the test strip within 15 seconds of sticking the fingertip.

In rare cases, Error Message 7 can occur in patients with long coagulation times (> 8 INR). If this error message appears again when the test is repeated, the result must be checked using another method.

The CoaguChek XS PT test strip may be used for patients under a combination therapy of oral anticoagulants plus heparin injections. Under no circumstances should heparinized capillary tubes be used for sample application. If capillary tubes are used, please use only the dedicated CoaguChek capillary tubes.

Error: Internal Error

An error occurred during the internal diagnostic test.



Solution:

Turn the meter off and remove the batteries. Wait at least 1 minute before re-inserting the batteries in the battery compartment. Re-set the date and time as described in the Meter Setup section of this manual.

Caution: The date and time must be set correctly.

Repeat the test. If you see the same error message again, the meter has a defect.

Other Information

Ordering Information for Health Care Professionals

Please contact Roche Diagnostics Customer Service at 1-800-428-5076.

	REF/Cat. Number
CoaguChek XS System (includes carrying case)	04837975001
CoaguChek XS PT Test 2 x 24 tests	04625315160
CoaguChek Lancets Box of 200	04348150001
Capillary Tubes/Bulbs	11621173001
CoaguWipe™ Bleach Towels	04515439001

Product Limitations

Please read the information packaged with the test strips regarding up-to-date product specifications and limitations.

Product Specifications

Operating Conditions

Temperature	+65°F to +90°F (+18°C to +32°C)
Relative humidity	less than 85% (without condensation)
Maximum altitude	14,000 feet (4300 m)
Placement	Operate the meter on a level, vibration-free surface or hold it so it is roughly horizontal.
Measuring range	Refer to test strip package insert.
Memory	100 test results with date and time
Interface	Infrared interface, LED/IRED Class 1
Battery operation	4 AAA batteries
Number of tests per set of batteries	Approx. 60 tests
Safety class	III
Automatic power-off	After 3 minutes
Dimensions	5.43 x 3.07 x 1.10 in (138 x 78 x 28 mm)
Weight	4.48 oz. or 127 g (without batteries)

Sample Material

Sample type	Capillary whole blood or non-anticoagulated venous whole blood.
Sample size	At least 10 µL
Interference	Refer to the test strip package insert.

Non-Operating Storage and Transport Conditions

Temperature range	-13°F to +158°F (-25°C to +70°C)
Relative humidity	10 to 85% (without condensation)

Support/Services

Questions

Please call the Roche Diagnostics Technical Service Center at 1-800-428-4674 if you have questions regarding the handling of your meter, the reliability of your results, or if you suspect the meter is defective.

Repairs

Please note that repairs, new settings or other modifications to the meter may only be performed by persons authorized by Roche Diagnostics.

Symbols

The following table lists all of the display screen icons and their meaning.

Symbol	Meaning
	Test strip (without sample application area)
	Test strip (with sample application area)
	Apply sample
	User must wait until the meter has completed an action.
24 h	24-hour time format
12 h	12-hour time format
am	Time between midnight and noon (in 12-hour time format)
pm	Time between noon and midnight (in 12-hour time format)
%Q	Indicates the results are displayed as a Quick percentage value.
Sec	Indicates the results are displayed in Seconds.
INR	Indicates the results are displayed in INR units.

Symbol	Meaning
On 🔔	Beep tone is turned on
OFF 🔔	Beep tone is turned off
↑ ↓	Result is above the chosen therapeutic range (only with INR as unit) Result is below the chosen therapeutic range (only with INR as unit)
88.8	• Results in the chosen unit • Error numbers
- - -	Memory contains no results or no further results
88:88	Displays the time in HH:MM format
88-88-88	Displays the date in DD-MM-YY, MM-DD-YY or YY-MM-DD format.
set	The monitor is in Setup Mode.
code	Indicates the code number of the code chip inserted in the meter.
> <	Result in the chosen unit is above the measuring range. Result in the chosen unit is below the measuring range.

Symbol	Meaning
	Battery status: • When the batteries still have their full charge, all segments are lit. • Individual segments disappear one by one as the batteries become weaker. • When there is no segment remaining, you can no longer perform a test. You can, however, still access the meter's memory.
mem	The meter is in Memory Mode.
	Automatic quality control completed successfully
error	Reports an error (see Error messages)
	Room or meter temperature is outside the acceptable range.
	Communication is taking place via the infrared interface
	Measurement chamber cover is open.

Warranty

CoaguChek XS Meter Limited (1 Year) Warranty

ROCHE DIAGNOSTICS warrants, to the original purchaser only, that the meter shall be free from all defects in material and workmanship for a period of one year from the date of purchase.

Purchaser's sole and exclusive remedy, with respect to the CoaguChek XS meter and parts thereof, shall be the repair and/or replacement of the meter or parts at Roche Diagnostic's option.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE DIAGNOSTICS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE METER. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FROM THE SALE OF THE COAGUCHEK XS METER. NO WARRANTY, EXPRESS OR IMPLIED (IF ANY), SHALL EXTEND FOR A LONGER DURATION THAN THE DURATION OF THE EXPRESS WARRANTY STATED ABOVE.

The foregoing warranty shall not apply to a meter which is damaged by accident or subject to alteration, misuse, tampering, and/or abuse, including the use of Dispatch® products. Meters which show damage or misuse will be handled in accordance with Roche Diagnostic's non-warranty service policy.

The warranty of the repaired/replacement meter will expire on the date of the original warranty expiration or ninety (90) days after shipment of a replacement system, whichever period is longer.

The following U.S. patents have been granted or are pending for the CoaguChek XS System (meter and test strips): 6,662,439; 7,073,246; 2005/0103624; 6,881,378; 6,207,000; 2005/0214171; 2005/0123441; 6,645,368; 2004/0157339; 2005/0129574; 2005/0135968

COAGUCHEK and COAGUWIPE are trademarks of Roche.

DISPATCH is a registered trademark of Caltech Industries, Inc.

© 2006 Roche Diagnostics. All rights reserved.

04837991001-0806

6658 Youree Dr Ste 180 PMB 404
Shreveport, La 71105
www.americanscreeningcorp.com
Sales@americanscreeningcorp.com
Toll Free: 1-866-526-2873
Ph: 318-798-3306 **Fax:** 318-798-3386

Diagnostics

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

www.coaguchek.com